K003094

OCT 2 5 2000

510(k) Summary

FastPack™ PSA Immunoassay and FastPack™ Analyzer System

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1.	**Submitter name, address, contact**	Qualigen, Incorporated 2042 Corte del Nogal Carlsbad, CA 92009	
		Telephone: Fax:	(760) 918-9165 (760) 918-9127
		Contact Person:	Dorothy Deinzer
		Date Prepared:	September 29, 2000
2.	**Device name**	Proprietary name:	FastPack™ PSA Immunoassay and FastPack™ Analyzer System
		Common name:	Chemiluminescence assay for the determination of Prostate-Specific Antigen (PSA). Photometer for clinical use.
		Classification Name:	Prostate-Specific Antigen (PSA) for Management of Prostate Cancer
3.	**Predicate device**	FastPack™ PSA Immunoassay on the FastPack™ Analyzer System (K994419)	

4. Device description

FastPack™ PSA Immunoassay Reagents

The FastPack™ PSA Immunoassay is a two-site chemiluminescence assay.

- Primary incubation: Sample, control or calibrator [100 µL] and PSA antibody solution [100 µL] react to form a sandwich complex.
- Secondary incubation: Streptavidin-coated paramagnetic particle solution is added to the reaction mixture. During this incubation, the sandwich complex is bound to the solid phase via the interaction of biotin and streptavidin.
- Removal of unbound materials: The paramagnetic particles are washed three times with wash buffer [0.2 mL/wash] to remove unbound materials.
- Substrate addition and detection: Chemiluminogenic substrate [140 µL] is added to the solid phase bound complex to form a chemiluminescent glow, which is measured by the FastPack™ Analyzer System.

FastPack™ Analyzer System

The FastPack™ Analyzer System is a compact chemiluminuescent immuoassay system. The system consists of four components:

- FastPack™ (Reagent Pack)
- FastPack™ Sample Dispenser
- FastPack™ Analyzer
- Pressure/Power Supply

The FastPack™ is a small essentially two-dimensional plastic package that contains all the pre-measured reagents, in sealed chambers, necessary to perform the desired test. The pack label contains a barcode with all necessary information required by the analyzer to run the test.

The FastPack™ Sample Dispenser delivers an accurate quantified sample (100 µL) of sample, calibrator or control for testing.

The FastPack™ Analyzer is designed to receive the FastPack™ and to perform the necessary assay by automatically mixing and moving the sample and reagents within the pack. The sample and reagents are moved from one chamber to another by applying uniform pressure to the compartments by means of pressure pads extended from the analyzer. The analyzer uses a small magnet to hold the paramagnetic particles during the wash phase. During the entire run of the FastPack™, temperature control is achieved by heating metal plates that adjoin the FastPack™.

5. Intended use

The FastPack™ PSA Immunoassay is a paramagnetic particle, chemiluminescence immunoassay intended for the *in vitro* quantitative determination of prostate-specific antigen (PSA) in human serum and plasma as an aid in the management of patients with prostate cancer. The FastPack™ PSA Immunoassay is designed for use with the FastPack™ Analyzer System.

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6. Comparison to predicate device

The modified FastPack™ PSA Immunoassay and FastPack™ Analyzer System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the recently cleared FastPack™ PSA Immunoassay and FastPack™ Analyzer System.

The following tables compare the modified FastPack™ Immunoassay System for PSA with the cleared FastPack™ Immunoassay System for PSA:

Similarities:

• Assay Methodology:	Sandwich immunoassay
• Detection:	Chemiluminescence
• Capture Antibody:	Monoclonal
• Label:	Alkaline Phosphatase
• Detector:	Photomultiplier Tube (PMT)
• Solid Phase:	Streptavidin-coated paramagnetic particles
• Substrate:	ImmuGlow™ (Indoxyl –3-phosphate and lucigenin)
• Data Analysis:	Internal data reduction via microcomputer
• Control Levels:	2
• Calibration Levels:	5
• Temperature Control:	Required
• Storage Condition:	2-8 °C
• Test Processing:	Automated
• Throughput:	Single sample
• Sample Volume:	100 uL
• Assay Range:	0 to 50 ng/mL
• Instrument Required:	FastPack™ Analyzer System
• Sample Cartridge:	All reagents included

Comparison to predicate device (continued)

Differences:

Feature	Cleared FastPack™ System	Modified FastPack™ System
Intended Use	For the *in vitro* quantitative determination of PSA in human serum as an aid in the management of patients with prostate cancer.	For the *in vitro* quantitative determination of PSA in human serum and plasma as an aid in the management of patients with prostate cancer.
Sample Type	Serum	Serum and Plasma
Master Curve Calibration Levels	5	6
Instrument Calibration	Factory generated master curve with daily two-level calibration adjustment	Factory generated master curve with a 30 day two-level calibration adjustment
Time to Result	30 minutes	15 minutes
Volume of Wash	3.0 mL	2.0 mL
Volume of Substrate	175 µL	140 µL

Performance Characteristics:

Spike Recovery	96 to 107%	88 to 127%
Dilution Recovery	94 to 120%	93 to 123%
Method Comparison	Serum versus Plasma using the FastPack™ PSA Immunoassay System: n = 130 Range of values (Serum): 0 to 49.1 ng PSA/mL Range of values (Plasma): 0 to 45.7 ng PSA/mL y = 0.9855x - 0.0597 (Deming) r = 0.97 (Pearson)	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Dorothy Deinzer
Director of Quality Assurance and
Regulatory Affairs
Qualigen, Inc.
2042 Corte del Nogal
Carlsbad, California 92009

OCT 2 5 2000

Re: K003094
Trade Name: FastPack™ PSA Immunoassay and FASTPack™ Analyzer System
Regulatory Class: II
Product Code: LTJ
Dated: September 29, 2000
Received: October 3, 2000

Dear Ms. Deinzer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 6

Indications for Use Statement

510(k) Number	K003094
Device Name	FastPack™ PSA Immunoassay and the FastPack™ Analyzer System
Indications for Use	The FastPack™ PSA Immunoassay is a paramagnetic particle, chemiluminescence immunoassay for the *in vitro* quantitative determination of prostate-specific antigen (PSA) in human serum and plasma. The FastPack™ PSA Immunoassay is indicated as an aid in the management of patients with prostate cancer. The FastPack™ PSA Immunoassay is designed for use with the FastPack™ Analyzer System.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maphis

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003094

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)